510(k) Summary:

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

This premarket notification has been submitted by Aloka Co., Ltd. and covers the Aloka SSD-4000 diagnostic ultrasound system and transducers. The address is:

10 Fairfield Boulevard Wallingford, CT 06492 (203) 269-5088

The contact person is Christopher M. Bohl, Technical Product Manager.

The proprietary name is the Aloka SSD-4000 diagnostic ultrasound system and transducers. The common name for this type of device is a diagnostic ultrasound system and transducers.

The item in this submission is covered under the following classification:

90 IYN	Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550
90 ITX	Diagnostic Ultrasound Transducer	21 CFR 892.1570
90 IYO	Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560

The above as stated in 21 CFR, part 892.1570, 1560 and 1550, has been classified as regulatory Class II.

The Aloka SSD-4000 and its transducers are substantially equivalent to the Aloka SSD-5500 and its transducers.

The Aloka SSD-4000 functions in the same manner as other diagnostic ultrasound devices. High frequency sound waves are transmitted into the body by a piezo-electric transducer. In the body, differences in the acoustic impedance of different tissues reflect a certain amount of the ultrasound energy back to the transducer, where it is transmitted via the probe cable to the system console and processed into an image. The Aloka SSD-4000 transducer can also use the Doppler shift of sound reflected from moving tissues (blood) to detect and display flow.

The Aloka SSD-4000, like other marketed diagnostic ultrasound systems and transducers is indicated for imaging body structures to aid in the diagnosis of disease or abnormality.

The Aloka SSD-4000 diagnostic ultrasound system and transducers are similar in technological characteristics to ultrasound systems and transducers marketed by Aloka and others:

- The SSD-4000 is indicated for the same diagnostic ultrasound applications as other products currently marketed by Aloka and others.
- The SSD-4000 has the same gray-scale and Doppler abilities as other products currently offered by Aloka and others.
- The SSD-4000 uses essentially the same technologies for imaging, Doppler functions and signal processing as other products currently marketed by Aloka and others.

- The SSD-4000 has the same method of use as other products currently marketed by Aloka and others.
- The SSD-4000 acoustic power output levels are below the maximum levels allowed by the FDA.
- The SSD-4000 is subjected to the same Quality Assurance systems in development and production as other products currently marketed by Aloka.
- The patient contact materials used in the SSD-4000 have been evaluated for safety via the same standards and methods as other products marketed by Aloka and others. These materials have been found to be safe for the intended uses.
- The SSD-4000 complies with the same electrical and physical safety standards as other products currently marketed by Aloka and others.
- Aloka Co., Ltd. Certifies that the SSD-4000 will comply with NEMA-UD2: 1992, AIUM 1994 "Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment", IIEC60601-1: 1988+A1: 1991+A2: 1995, UL-544: Third Edition and ISO10993-1: 1997. All testing will be complete and the results will meet the requirements of the standards above at the time of market introduction.



DEC 2 7 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Aloka Co., Ltd. c/o Mr. Donald James Sherratt Medical Stream Director Intertek Testing Services NA, Inc. 70 Codman Hill Road Boxborough, MA 01719

Re: K003739

Aloka SSD-4000 (Diagnostic Ultrasound Imaging System)

Regulatory Class: II

21 CFR 1550/Procode: 90-IYN 21 CFR 1560/Procode: 90-IYO 21 CFR 1570/Procode: 90-ITX Dated: November 20, 2000 Received: December 4, 2000

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SSD-4000, as described in your premarket notification:

UST-995-7.5, UST-990-5, UST-987-7.5, UST-979-3.5, UST-9104, UST-9121, UST-9123, UST9124, UST-579T-7.5, UST-670P-5, UST-672-5/7.5, UST-9101-7.5, UST-5299, UST-5524-7.5, UST-5526L-7.5, UST-5534T-7.5, UST-5536-7.5, UST-5542, UST-5710-7.5, UST-5268P-5, UST-5293-5, and UST-5298.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device-as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its tollfree number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D. at (301) 594-1212.

Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Indications for use statement

Device Name:

Indications For Use:

(Per 21 CFR 801.109)

		The subject Aloka SSD-4000 is an all-digital diagnostic ultrasonic scanner with a digital beamformer supporting gray scale, spectral Doppler and Color Flow imaging. It is based upon and substantially equivalent to the Aloka SSD-5500 system, which received clearance for market under K963616. The SSD-4000 is also equivalent to other high performance digital beamforming systems such as the ATL HDI-5000 and Vingmed (G.E.) System V.
		The Aloka SSD-4000 is a Track 3 system. Its maximum acoustic outputs are below the pre-amendments upper limits and it conforms to the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment". The maximum thermal index is below 6.0. Depending on the probe, the Aloka SSD-4000 may be used for diagnostic ultrasound imaging in Cardiac, Gynecological, Neurological, Obstetrical, Neonatal, Pediatric, Perinatal, Radiological, Vascular, Urological, Trauma and Surgical applications.
	e en	The Aloka SSD-4000 is not indicated for ophthalmic applications.
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	(PLEASE DO NO	T WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
	(FEEE EE EE	Concurrence of CDRH, Office of Device Evaluation (ODE)
		(Division Sign-Off)
		Division of Reproductive, Abdominal, ENT,
		and Radiological Devices
	Prescription use	510(k) Number K 003739 OR Over-The-Counter Use

Aloka SSD-4000 Diagnostic Ultrasound System

The specific indications for use form for the SSD-4000 system is

for each ultrasonic probe is given on pages 13 to 34 of the submission. The system's indications for use are given below:

given on page 12B of the submission. The indication for use form

4.3.1

Diagnostic Ultrasound Indications for Use Form SSD-4000

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В.	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal		N	N	N	N	N	N		See Below				
Abdominal		N	N	N	N	N	N		See Below				
Intraoperative (specify)		N	N	N	N	N	N		See Below				
Intraoperative Neurological		N	N	N	N	N	N	(Marie Const.)	See Below	36 77 99 (1 1 38)			
Pediatric		N	N	N	N	N	N _		See Below				
Small Organ (specify)		N	N	N	N	N	N	es e la especiale de la especi	See Below	e affire to the market			
Neonatal Cephalic		N	N	N	N	N	N	acomo spajendaj	See Below	e jedana i se tijara			
Adult Cephalic		N	N	N	N	N	N		See Below				
Cardiac		N	N	N	N	N	N	A PARTO OF THE PROPERTY OF	See Below	nower, or survey,			
Transesophageal		N	N	N	'N	N	N	en en 'entresense et	See Below	renar lasse			
Transrectal		N	N	N	N	N	N		See Below				
Transvaginal		N	N	N .	N	N	N		See Below	e serverti (i sence			
Transurethral									- Artist	. Stem			
Intravascular										-			
Peripheral Vascular		N	N	N	N	N	N		See Below	1 100 000			
Laparoscopic		N	N	N	N	N	N		See Below	a mas a coms			
Musculo-skeletal Conventional		N	N	N	N	N	N		See Below				
Musculo-skeletal Superficial		N	N.	N	N	N	N		See Below				
Other													

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder. Small pass applications include breast, testes and thyroid.

Division of Reproductive, A

Division of Reproductive, Abdominal, ENT,

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and Radiological Devices
ON ANOTHER PAGE IF 100 8739

UST-995-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal													
Intraoperative (specify)		P	P	P		P	P		See Below				
Intraoperative Neurological													
Pediatric													
Small Organ (specify)		P	P	P		P	P		an Sawar na and a troubles	10., 10.00 ° 93.01			
Neonatal Cephalic								district subjection	Committee of the special control of the second south	and the second			
Adult Cephalic													
Cardiac		1								<u> </u>			
Transesophageal		1						on the state of th	Literatura saatu ka maka satu sa	1.15 p. 190.38			
Transrectal													
Transvaginal				<u> </u>									
Transurethral								and the second of the second of the	the garden har have believed	1 5 S S S S S S S S S S S S S S S S S S			
Intravascular		1											
Peripheral Vascular		P	P	P		P	P		See Below	1			
Laparoscopic		-						<u> </u>	e produced to select a conserva-				
Musculo-skeletal Conventional													
Musculo-skeletal													
Superficial Other	-			·					nna weet out we leed	a sampa maga			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

<u>Intraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast, testes and thyroid.</u>

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

UST-990-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal		N	N	N		N	N		See Below				
Abdominal		N	N	N		N	N		See Below				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric													
Small Organ (specify)								(a) (%)	and the second seco	Sir sides, av			
Neonatal Cephalic								on consultation		. / / Albert / / /			
Adult Cephalic		 											
Cardiac		<u> </u>							· · · · · · · · · · · · · · · · · · ·				
Transesophageal								ang tina tinang menintersya	the first of the set page.	griss sammer			
Transrectal													
Transvaginal													
Transurethral								, the most of year but his day	er groenhalas in ing	ar in the second			
Intravascular													
Peripheral Vascular					 								
Laparoscopic								Maria Contactor	e sera em la sera de	2 (5), (4), (5), (4)			
Musculo-skeletal Conventional									100000000000000000000000000000000000000				
Musculo-skeletal Superficial													
Other									t est est est est	i grangasi			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off) Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003739

UST-987-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal		-yo											
Intraoperative (specify)		P	P	P		P	P		See Below				
Intraoperative Neurological													
Pediatric													
Small Organ (specify)									- Julius Bernaugaster georg	100000000000000000000000000000000000000			
Neonatal Cephalic		P	P	P		P	P	www. csa	See Below	t di minakan N			
Adult Cephalic			<u> </u>										
Cardiac								18 18 1 No. 18 18 18 18 18 18 18 18 18 18 18 18 18		3431			
Transesophageal			 					to the substantial states	Stage of Superior Administra	1.00			
Transrectal													
Transvaginal									- u				
Transurethral								operates en	the state of the second	ta jake			
Intravascular													
Peripheral Vascular													
Laparoscopic								4		t e a a e a			
Musculo-skeletal Conventional								190					
Musculo-skeletal Superficial									•				
Other) 						W. C.	i i samaka			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003739

UST-979-3.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal		P	P	P		P	P		See Below				
Abdominal		P	P	P		P	P		See Below				
Intraoperative (specify)								·					
Intraoperative Neurological							:						
Pediatric								-,,	·				
Small Organ (specify)									tota e e e e e e e e e e e e e e e e e e e	AL STATE			
Neonatal Cephalic								; A ₉ py	e metal alemania (m	t i setting			
Adult Cephalic													
Cardiac									<u> </u>				
Transesophageal								on at the second	than a wife to straight	1. 1. 1. 1. 1. 2.			
Transrectal													
Transvaginal		1											
Transurethral								77 3.3 3963	Superior getta	e toward la			
Intravascular													
Peripheral Vascular		<u> </u>											
Laparoscopic								Al est	a distribution of the second	n senset ne			
Musculo-skeletal Conventional													
Musculo-skeletal Superficial									rain in nagyara				
Other									A ng Histori A	e de la companie			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT
and Radiological Devices
510(k) Number K003739

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal													
Intraoperative (specify)		N	N	N		N	N		See Below				
Intraoperative Neurological													
Pediatric													
Small Organ (specify)									, Negriska am oseg	લ પ્રાપ્ય ર			
Neonatal Cephalic		N	N	N		N	N	e europaki	See Below				
Adult Cephalic													
Cardiac	<u> </u>							~ Ca.274 - S	11 12 15 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	5. 7998			
Transesophageal		<u> </u>						and the second second	COLOR TO SERVICE STORY				
Transrectal									-				
Transvaginal								- Cincolina					
Transurethral								i promer	satura y is ma				
Intravascular													
Peripheral Vascular	<u> </u>												
Laparoscopic								·	11 to 12 to 12 to				
Musculo-skeletal Conventional									1.4.1.71 (1.4.18				
Musculo-skeletal Superficial													
Other							4		ige . in	1, 11 14.24			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number IC 00 3 7-3 9

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic						1							
Fetal		N	N	N		N	N		See Below				
Abdominal		N	N	N		N	N		See Below				
Intraoperative (specify)													
Intraoperative Neurological									والمراجع المراجع المراجع	1.44			
Pediatric													
Small Organ (specify)								-441.1.	ty sits in leadings.	1			
Neonatal Cephalic								, i stantik četa	- on attribute at the work	and the second of the			
Adult Cephalic								Pour Control of Control					
Cardiac													
Transesophageal								10 J. 12/20 (12/20) A 10/15/19/	Sistemany of the part of the ag	ang terlegy in the contra			
Transrectal													
Transvaginal			1										
Transurethral								at an in the section	unitarian la	n in the same			
Intravascular													
Peripheral Vascular													
Laparoscopic								W. O. S.	special sections				
Musculo-skeletal Conventional								as Mary 1	s, se la conse				
Musculo-skeletal Superficial													
Other									Angelia in				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number <u>K063739</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal		N	N	N		N	N		See Below			
Abdominal		N	N	N		N	N		See Below			
Intraoperative (specify)			1									
Intraoperative Neurological												
Pediatric	 											
Small Organ (specify)									erke — Herrich Schauß	7		
Neonatal Cephalic								. complete	deplete and two deals, increased.	. 41 - 1,429, 34.3		
Adult Cephalic			 									
Cardiac						<u> </u>						
Transesophageal			\vdash					The second secon	gartin o spanjena grajena	a ja a sa		
Transrectal			 									
Transvaginal												
Transurethral	<u> </u>			<u> </u>				1 Section 2	Section 2 of the second			
Intravascular			_	!	<u> </u>							
Peripheral Vascular			-			-						
Laparoscopic		ļ	\vdash					n en	proteine in the			
Musculo-skeletal		 	├		 							
Conventional			<u> </u>						rit inswertig			
Musculo-skeletal Superficial												
Other									i in the second	. 14. 46.		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003739

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					M	lodes of ope	ration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal		N	N	N		N	N		See Below	
Abdominal										
Intraoperative (specify)									-	
Intraoperative Neurological									و ما المادة	
Pediatric										
Small Organ (specify)									, asserba k	() () () () () () () () () ()
Neonatal Cephalic			-					্তা ভুগক্তপথ	in the decrease and thought that	Land to the one of
Adult Cephalic								n en oorden skriger gelek kroefte	ray may they share the	
Cardiac										
Transesophageal								. how farth expansion	, off also garden and the const	11 + 114+0340
Transrectal								Lance of content was		
Transvaginal		N	N	N		N	N		See Below	
Transurethral								er in pastoria	and a separate of the second	and the section
Intravascular										
Peripheral Vascular								ومدائد فالمدنسية والمه		
Laparoscopic					1			*	* **	, capparen
Musculo-skeletal Conventional									g gayet Par	e tetra i julija ja
Musculo-skeletal Superficial						·				
Other									. 5707.000 5	The state of the s

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 00 37 39

UST-579T-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal													
Intraoperative (specify)		P	P	P		P	P		See Below				
Intraoperative Neurological									and the Paper of Section				
Pediatric		 											
Small Organ (specify)		P	P	P		. P	P	10.36	See Below				
Neonatal Cephalic								y granis	er de de la companya	raye netty2			
Adult Cephalic		 											
Cardiac								1 (4 - 1.44 (Serbour Southern Control of Conservation				
Transesophageal								a versión seu o companyo	e police of pacetings in the states	a Takasa			
Transrectal										<u> </u>			
Transvaginal							*	4	-1				
Transurethral							**	a the time of the test	ang transport	4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
Intravascular		<u> </u>	 							 			
Peripheral Vascular		P	P	P		P	P		See Below				
Laparoscopic							14		the satisfies				
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other									e 1 4.4.				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

<u>Intraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast, testes and thyroid.</u>

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number Koo3739

UST-670P-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic					·							
Fetal												
Abdominal												
Intraoperative (specify)									······································			
Intraoperative Neurological												
Pediatric												
Small Organ (specify)									and the area of the second	, arte e e e e e e e e e e e e e e e e e e		
Neonatal Cephalic	 							2 17.2%	Johnson og vist 1882 af Mil	all the selection		
Adult Cephalic			1									
Cardiac			 					sale a la competización	1988 1898	1 51 7 51 7 50 7 50 50 50 50 50 50 50 50 50 50 50 50 50		
Transesophageal								entron e jangeratujake	o o o o o o o o o o o o o o o o o o o	1,449/5432		
Transrectal		P	P	P		P	P		See Below			
Transvaginal		P	P	P		P	P	es a francisco et de autorio de a	See Below			
Transurethral								and medit in the brokes of the	of the Section of the	op to a sign		
Intravascular												
Peripheral Vascular		<u> </u>										
Laparoscopic								un (1840 hg.)	, and the state of	a se consequence of		
Musculo-skeletal Conventional									11.0	1. Tak 2.75		
Musculo-skeletal Superficial												
Other									11.50 11.50	e i jedeno godini i s		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K 00 2 7 3 9

UST-672-5/7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic					****								
Fetal		1											
Abdominal													
Intraoperative (specify)		P	P	P		P	P		See Below				
Intraoperative Neurological													
Pediatric													
Small Organ (specify)		<u> </u>	 						e je ni Kojesjo	serve ora san			
Neonatal Cephalic								, res ₂	e, se ogsette, e ogsjetog	sili i sergose			
Adult Cephalic													
Cardiac								19.2 11 (2.5 mg ⊈ g 2 mg ²	g um cedebyte v tygzus	. The state of the			
Transesophageal								a Contractor	o en sue la companya de la companya	an en			
Transrectal		P	P	P	/ - ,, ,, 	P	P		See Below				
Transvaginal								30 S.C. 30 Th. 18 S					
Transurethral	<u> </u>							agra sa sa sa sa	and the state of t				
Intravascular													
Peripheral Vascular													
Laparoscopic							·		1.55- 0	95.0			
Musculo-skeletal Conventional	,								vin Laterate	e e e e e e e e e e e e e e e e e e e			
Musculo-skeletal Superficial													
Other													

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K 003739

UST-9101-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal		N	N	N		N	- N		See Below				
Abdominal		N	N	N		N	N		See Below				
Intraoperative (specify)													
Intraoperative Neurological		1											
Pediatric		N.	N	N		N	N		See Below				
Small Organ (specify)		1	 						্রক্তিকের ও ক্রেক্স	Page Sayte			
Neonatal Cephalic								14 1.51	Conjection of Control of the Life Control	" "House Read and			
Adult Cephalic									Turke the entertrick to the the sea				
Cardiac								Augens in page vent					
Transesophageal		1						Francis Services Service	egende og af egendera	the transfer of the second			
Transrectal													
Transvaginal								A SALLEY AND A STATE OF THE STATE OF THE SALES	A CONTRACTOR OF THE CONTRACTOR				
Transurethral								Service Sections	the same of the transfer of the same of th	tin terdan, in			
Intravascular													
Peripheral Vascular													
Laparoscopic								.*#	· · · · · · · · · · · · · · · · · · ·	en e			
Musculo-skeletal Conventional									e i e e e e e e e e				
Musculo-skeletal Superficial										,			
Other						,				1 1 1 2 1 2 V h			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 003739

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic								·					
Fetal		N	N	N	N	N	N		See Below				
Abdominal		N	N	N	N	N	N		See Below				
Intraoperative (specify)													
Intraoperative Neurological	-												
Pediatric			-										
Small Organ (specify)									e ma _{ne} eng	চনত চনক্র			
Neonatal Cephalic								V4	man i wake mag	150 - 50 85			
Adult Cephalic													
Cardiac		N	N	N	N	N	N		See Below				
Transesophageal								Assert Francisco	·	·			
Transrectal													
Transvaginal				<u> </u>									
Transurethral								্রতিক হল	nn nn seine eile eile eile eile eile eile eile	nan e			
Intravascular													
Peripheral Vascular										·-			
Laparoscopic										ta ja ta			
Musculo-skeletal Conventional									, system	tet steet			
Musculo-skeletal Superficial										,			
Other									, 1979,	1			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number / 003739

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal													
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric													
Small Organ (specify)		P	P	P		P	P	The good	See Below	the state of the s			
Neonatal Cephalic								, et in e in e	and the second s	TO STANGE A			
Adult Cephalic								10 PM - 10 PM					
Cardiac		1	†		1								
Transesophageal		1						a a sa na balaya in Ta Shipkar	. Has interested the same region	an un un explandes			
Transrectal													
Transvaginal													
Transurethral		1	 					Tarris Secretaria	san san makabagan ara	t ta a said			
Intravascular		1											
Peripheral Vascular		P	P	P		P	P		See Below				
Laparoscopic			T					117.73	san than the	H of the state of			
Musculo-skeletal Conventional								14,70	sussessing				
Musculo-skeletal Superficial									N. Jan				
Other									e, sue	The second secon			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Small parts applications include breast, testes and thyroid.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number <u>K003739</u>

UST-5526L-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		P	P	P		P	P		See Below			
Intraoperative Neurological									* *			
Pediatric												
Small Organ (specify)								- Marks	in the street of the safe	17.77		
Neonatal Cephalic								. F. F. 1. 5 18 18	a temperatura	reserved a consession		
Adult Cephalic												
Cardiac	1		1					2, 200-01				
Transesophageal									on the second of the second			
Transrectal												
Transvaginal										7 . · · · · · · · · · · · · · · · · · ·		
Transurethral		1	<u> </u>					1. 7%, 8%	e e e e e e e e e e e e e e e e e e e	to an		
Intravascular												
Peripheral Vascular			 									
Laparoscopic		P	P	P	1	P	P		See Below			
Musculo-skeletal Conventional								·	- 15-4- Ti 18-4	M		
Musculo-skeletal Superficial												
Other									Station.			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Ovision of Reproductive, Abdominal, ENT, and Radiological Devices

SEO(k) Number K003739

UST-5534T-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		N	N	N		N	N		See Below	·		
Intraoperative Neurological												
Pediatric												
Small Organ (specify)		N	N	N		N	N		See Below	u serio i i carad		
Neonatal Cephalic							-	Se control	JANES STANDARD OF THE	u iz — — — — — — — — — — — — — — — — — —		
Adult Cephalic								Julian di Handari Nafi	ar an and the control of the control	1 - No - 200s		
Cardiac												
Transesophageal								in a supplemental	and the same particles and the	esperiment of esper		
Transrectal												
Transvaginal												
Transurethral								, po monetario presidente	in at what was a specific to the			
Intravascular												
Peripheral Vascular		N	N	N		N	N		See Below			
Laparoscopic					:			5.8 4.84	n na nijewan			
Musculo-skeletal Conventional										30		
Musculo-skeletal Superficial												
Other										1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

<u>Intraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast, testes and thyroid.</u>

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

\$10(k) Number <u>K003739</u>

UST-5536-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

		* Transaction			M	lodes of ope	ration			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)									gravery de 100 gravità	ra i na gret at eta arak
Neonatal Cephalic								1 Million	wysia i sassa i sys	and the second
Adult Cephalic										
Cardiac										
Transesophageal	<u> </u>							. The second	non and designed the state and	ester i i i i i i i
Transrectal										
Transvaginal										
Transurethral								ens suppressed	90% 900	
Intravascular		1								
Peripheral Vascular										
Laparoscopic		P	P	P		P	P	Tre a styllage	See Below	
Musculo-skeletal Conventional								A ²⁵		
Musculo-skeletal Superficial										
Other						1				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: include liver, pancreas and gall bladder.

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(Division Sign-Off)	
Division of Reproductive, Abdominal, EN	I
and Radiological Devices	

UST-5542

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)		N	N	N		N	N		See Below	in ye inskrige		
Neonatal Cephalic								. 15 m 14 h 14	Para Profession and	ayrah ya ta asaa sa sa		
Adult Cephalic												
Cardiac		<u> </u>							×			
Transesophageal								i e mari energentan	sange i tradició socialeses	10 10 10 10 10 10 10 10 10 10 10 10 10 1		
Transrectal		<u> </u>										
Transvaginal		1										
Transurethral								ು ಅಗಳು.ಭಾಷ	. grown were personal	1117640		
Intravascular		1										
Peripheral Vascular		N	N	N		N	N		See Below			
Laparoscopic												
Musculo-skeletal Conventional		N	N	N		N	N		See Below			
Musculo-skeletal Superficial		N	N	N		N	N		See Below			
Other				1						1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Small parts applications include breast, testes and thyroid.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number Koo3739

UST-5710-7.5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

**************************************					N	lodes of ope	ration			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic				-						
Fetal					-					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric	· · · · · · · · · · · · · · · · · · ·									
Small Organ (specify)		N	N	N		N	N	.64	See Below	9.1.1.4
Neonatal Cephalic				,			_		. Charanagara	
Adult Cephalic										
Cardiac										
Transesophageal								j. 14. 14. 14. 14. 14. 14. 14. 14. 14. 14	es, sector y the estimate	11.1.1.1
Transrectal										
Transvaginal										
Transurethral								19800274	· January and a second	
Intravascular										
Peripheral Vascular										
Laparoscopic								÷	n na na na	
Musculo-skeletal Conventional									1 (A.1)	
Musculo-skeletal Superficial										
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Small parts applications include breast, testes and thyroid.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number 1<003739

UST-5268P-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					N	lodes of ope	ration		, , , , , , , , , , , , , , , , , , ,	
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal								·		
Abdominal								·		
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological		P	P	P		P	P		See Below	
Pediatric										
Small Organ (specify)		P	P	P		P	P	- 24	See Below	Fay 1
Neonatal Cephalic								a . ster	·	
Adult Cephalic			ł						-	
Cardiac			ļ							
Transcsophageal										
Transrectal			1							
Transvaginal			T							
Transurethral	•		 					ent in the graph	on the	
Intravascular		<u> </u>	_							
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic			†						,	
Musculo-skeletal Conventional								2		
Musculo-skeletal Superficial								All control of the co		
Other										1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

<u>Intraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast, testes and thyroid.</u>

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003739

UST-5293-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

					N	lodes of ope	ration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)									. 1904.000	
Neonatal Cephalic							NA.		terraren 1	W. 1
Adult Cephalic		ļ								
Cardiac	<u> </u>									
Transesophageal		N	N	N	N	N	N		See Below	
Transrectal										
Transvaginal	1							· #***		
Transurethral	1									
Intravascular				 						
Peripheral Vascular										
Laparoscopic							· .			
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other	 								-	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003739

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic				·								
Fetal												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric		N	N	N	N	N	N		See Below			
Small Organ (specify)												
Neonatal Cephalic								1.31.60				
Adult Cephalic												
Cardiac		N	N	N	N	N	N	2 (1980	See Below			
Transesophageal										·		
Transrectal												
Transvaginal								5				
Transurethral									inski ya			
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial									Section 18			
Other												

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003739